

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: BRADLEY K. GROFF GARDNER GROFF, P.C. PAPER MILL VILLAGE, BUILDING 23 600 VILLAGE TRACE, SUITE 300 MARIETTA, GA 30067

Date of mailing (day/month/year)	14 JUN 2005
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Applicant's or agent's file reference 2G02.2-0831		FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/US04/26971	International filing date (day/month/year) 19 August 2004 (19.08.2004)	Priority date (day/month/year) 20 August 2003 (20.08.2003)	
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61B 17/32 and US Cl.: 606/182			
Applicant FACET TECHNOLOGIES, LLC			

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Michael Thale Telephone No. (703) 308-0858
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US04/26971

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
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Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-48</u>	YES
	Claims <u>NONE</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-48</u>	NO
Industrial applicability (IA)	Claims <u>1-48</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-14 lack an inventive step under PCT Article 33(3) as being obvious over Mawhirt et al. (5,797,940). Mawhirt et al. disclose housing 12, lancet 52, 58 and member 32, 36 which is obviously a shutter since it is movable between an open position and a closed position retaining the lancet in the retracted position (col. 6, lines 44-49).

Claims 15-28 and 44-48 lack an inventive step under PCT Article 33(3) as being obvious over Davis et al. (6,156,050). Davis et al. disclose housing 42, lancet 174 and mechanism 38 which is obviously a charging mechanism since it includes loading recess (the recess near stop 68) and loading tab 70 that it rotated and retained in the loading recess.

Claims 29-43 lack an inventive step under PCT Article 33(3) as being obvious over Munsch et al. Munsch et al. disclose housing 11 or 25, lancets 13 and a carousel that includes a carrier 12 that it adapted for carrying the lancets in a non-radial configuration (i.e. the lancet is in a non-radial configuration when it is oriented out of the plane of the carrier either when it is cocked or when it pierces the finger as described in col. 2, lines 35-44).

Claims 1-48 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.